

**ENVIRONMENTAL PROTECTION AGENCY****40 CFR Part 721**

[OPPTS-50618; FRL-4766-6]

RIN 2070-AC37

**Significant New Uses of Lead**

AGENCY: Environmental Protection Agency (EPA).

ACTION: Advance notice of proposed rulemaking (ANPR).

**SUMMARY:** EPA is exploring the possibility of issuing significant new use rules (SNURs) for certain uses of elemental lead (Pb) and lead compounds under section 5(a)(2) of the Toxic Substances Control Act (TSCA). The SNURs would require persons to notify EPA at least 90 days before commencing the manufacture, import, or processing of lead and lead compounds for uses identified by the Agency as significant new uses. The significant new use notice (SNUN) would provide EPA with the opportunity to evaluate the intended use and associated activities and to prevent potentially unreasonable risk of injury to human health and the environment from occurring. EPA is issuing this ANPR to: (1) Communicate its intention to regulate significant new uses of elemental lead and lead compounds; (2) identify components of its proposed regulatory approach; (3) request comment on issues related to this approach; and (4) request comment and information on existing uses of lead that would help support EPA's selection of proposed criteria for defining significant new uses of lead. The Agency is particularly concerned with products the use of which may pose unreasonable risks to children. The information submitted in response to this ANPR will help EPA design an effective and efficient strategy for regulating significant new uses of lead. **DATES:** Written and electronic comments in response to this ANPR must be received on or before November 28, 1994.

**ADDRESSES:** All written data and comments should be submitted in triplicate to OPPT Document Control Officer (7407), Office of Pollution Prevention and Toxics, Environmental Protection Agency, Rm. E-G99, 401 M St., SW., Washington, DC 20460. All written data and comments should be identified by the docket number OPPTS-50618.

Comments and data may also be submitted electronically by any of three different mechanisms: by sending

electronic mail (e-mail) to: Docket-OPPTS@epamail.epa.gov; by sending a "Subscribe" message to listserver@unixmail.rtpnc.epa.gov and once subscribed, send your comments to RIN-2070-AC37; or through the EPA Electronic Bulletin Board by dialing 202-488-3671, enter selection "DMAIL," user name "BB—USER" or 919-541-4642, enter selection "MAIL," user name "BB—USER." Comments and data will also be accepted on disks in WordPerfect in 5.1 file format or ASCII file format. All comments and data in electronic form should be identified by the docket number OPPTS-50618. Electronic comments on this ANPR, but not the complete record, may be viewed or new comments filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found in Unit VII. of this document.

Data and comments in written form containing information claimed as confidential business information (CBI) should be submitted in triplicate to: OPPT Document Control Officer (7407), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460, Attention: OPPTS-50618. A sanitized copy of the comments that can be included in the public docket must be provided in triplicate to the OPPT Document Control Officer. Further information on submitting comments containing information claimed as CBI is provided in Unit VIII. of this document. No CBI should be submitted through e-mail.

**FOR FURTHER INFORMATION CONTACT:** For general information contact: Susan B. Hazen, Director, Environmental Assistance Division (7408), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460, Telephone: 202-554-1404, TDD: 202-554-0551. For technical information contact: Jonathan Jacobson, Chemical Management Division (7404), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460, Telephone: 202-260-3779, Internet: jacobson.jonathan@epamail.epa.gov.

**SUPPLEMENTARY INFORMATION:** Reducing human exposure to lead and lead contamination of the environment continue to be priority issues for EPA. Exposure to lead can result in a variety of adverse human health effects in both children and adults. Recent research and scientific evidence indicate that human health effects (e.g., impaired neurological development) occur at low exposure levels. Lead contamination of

the environment is causing degradation of habitat and lead products have been implicated in the death of individual animals from several species.

In response to these problems, EPA has undertaken a variety of regulatory, programmatic, and research efforts to evaluate and address the environmental impacts of lead. Since 1991, Agency activities have been coordinated through the *Strategy for Reducing Lead Exposures*. This strategy includes regulatory and pollution prevention activities, a lead abatement program for "in-place" lead, and a research program. The promulgation of SNURs for elemental lead and lead compounds is part of EPA's multi-faceted strategy for reducing unacceptable lead exposures.

EPA's efforts are designed to reduce exposure to lead by: (1) Preventing new uses and phasing out current uses of lead that pose unreasonable risks; (2) controlling lead emissions; (3) managing the disposal of lead-containing wastes; (4) addressing in-place lead; and (5) supporting research to improve EPA's ability to assess and reduce lead-related risks.

**I. Authority**

Section 5(a)(2) of TSCA (15 U.S.C. 2604(a)(2)) authorizes EPA to determine that a use of a chemical substance is a "significant new use." The Agency must make this determination by rule after considering all relevant factors, including those listed in section 5(a)(2). Section 5(a)(2) factors generally relate to the extent to which a use changes the volume of a chemical's production or the type, form, magnitude, or duration of exposure to it. Once EPA determines that a use of a chemical substance is a significant new use, section 5(a)(1)(B) of TSCA requires persons to submit a notice to EPA at least 90 days before they manufacture, import, or process the chemical substance for that use.

Persons subject to a SNUR would comply with the same notice requirements and EPA regulatory procedures as submitters of premanufacture notices (PMNs) under section 5(a)(1)(A) of TSCA. In particular, these requirements include the information submission provisions of section 5(b) and (d)(1), the exemptions authorized by section 5(h)(1), (2), (3), and (5), and the regulations at 40 CFR part 720. The premanufacture notification process provides EPA the opportunity to review the particular use of the chemical substance and make a reasonable risk determination prior to the use's commercial introduction. Following its review, EPA may take regulatory action under section 5(e), 5(f), 6, or 7 to control the activities for

which it has received a SNUN. If EPA does not take action, section (5)(g) of TSCA requires EPA to explain in the *Federal Register* its reasons for not taking action.

Persons who intend to export a substance identified in a final SNUR are subject to the export notification provisions of TSCA section 12(b). The regulations that interpret section 12(b) appear at 40 CFR part 707. Persons who import a substance identified in a final SNUR must certify that they are in compliance with TSCA, which includes the SNUR requirements. The EPA import certification requirements appear at 40 CFR part 707.

## II. Uses of Lead

Lead is a soft, gray metallic element mined from rock and found in its natural state all over the world. It is virtually indestructible and non-biodegradable. Its malleability, low melting point, ease of processing, abundance, low cost, density, lubricant properties, and durability give it good functional value.

In 1992, the U.S. Bureau of Mines reported that U.S. industries consumed over 1.24 million tons of lead. Of this quantity, nearly 81 percent was used to manufacture storage batteries and 5 percent was used in the ammunition industry. Other uses include: Glass and ceramics; lead chemical products; cable coverings; lead sheet; lead solder; casting lead; pigments; pipes, traps, and other extruded products; brass and bronze; other metal products; heat stabilizers; and bearing metals. Manufacturers use lead in its elemental form, in compounds including lead oxides and lead chromate, and in alloys (e.g., brass and solder).

## III. Human Health Effects

Exposure to lead can produce a spectrum of human health effects across a wide range of exposure levels. Recent studies indicate that these toxic effects may occur at exposure levels considerably lower than previously recognized. Accordingly, the Centers for Disease Control and Prevention (CDC) has established the threshold of concern for blood lead (PbB), the most common index of lead exposure, at 10 µg/dL.

Young children and fetuses are especially vulnerable to lead: the nervous systems are developing and lead is absorbed into the blood stream more easily than in adults. High PbB levels (>40–60 µg/dL) in children are associated with anemia, mental retardation, and encephalopathy. At extremely high levels (>100 µg/dL), death may occur. There is also a concern that high lead exposure might

play a role in spontaneous abortions. At lower exposure levels, lead has been linked to impaired cognitive performance, delayed neurological and physical development, decreased birth weight, and interference with heme synthesis and Vitamin D metabolism.

Recent research indicates that deficits in IQ and other measures of cognitive functions have been associated with PbB levels of 10 µg/dL (Bellinger, D.C., Stiles, K.M., and Needleman, H.L.; "Low-Level Lead Exposure, Intelligence and Academic Achievement: A Long-Term Follow-up Study"; *Pediatrics*; 1992; vol. 90; pp. 855–861). EPA, in its *Air Quality Criteria for Lead, Volumes I–IV and Addendum* (USEPA, 1986) and its *Air Quality Criteria for Lead, Supplement to 1986 Addendum* (USEPA, 1990), has identified the following relationships between lead exposure and human health:

1. Deficits in mental indices have been found in infants with maternal or umbilical cord PbB levels as low as 6–7 µg/dL.

2. Low birth weights and decreased gestation age, factors that may influence early neurological development have been associated with infants born to women with PbB levels above 12–14 µg/dL and possibly as low as 7 µg/dL.

3. Early childhood growth reductions have been associated with PbB levels from 5–35 µg/dL.

In its study *Measuring Lead Exposure in Infants, Children, and Other Sensitive Populations*, the National Academy of Sciences documented a similar range of effects (NAS, 1993). The Academy noted that PbB concentrations around 10 µg/dL are associated with disturbances in early physical and mental growth and in later intellectual functioning and academic achievement.

Although Federal government interest in lead poisoning has primarily focused on children, there is substantial evidence that lead exposures can produce adverse health effects in adults. Of great concern is evidence that elevated PbB levels have been associated with slight increases in blood pressure. Because lead is stored in bone, it may be mobilized during periods of stress or greater metabolic demands for calcium (e.g., pregnancy).

## IV. Environmental Effects

Lead is one of the most common toxic substances found in large and small animals. Lead poisoning is the most frequently diagnosed toxicological problem in veterinary medicine; its occurrence has been reported in all domestic species and in several species of zoo animals. Lead poisoning has also affected many major species of

waterfowl in North America and has been reported in many birds elsewhere in the world. Sources of these exposures have typically included lead wastes, lead paint, spent lead shot, fishing sinkers, and contaminated forage near smelters and roadways.

Laboratory and field data show that at high concentrations, lead can affect certain plants and inhibit photosynthesis, reduce growth, and alter species composition. Other studies indicate that high lead concentrations alter the composition of soil microbial communities and inhibit invertebrate activity resulting in delayed decomposition of organic matter, reduced nutrient supply, and altered soil properties, such as lower organic content.

Lead is toxic to many phyla of aquatic biota. Water lead concentrations as low as 19 to 30 µg/L have been associated with increased mortality and impaired reproduction in aquatic invertebrates. Aquatic vertebrates (e.g., fish) appear to be even more sensitive. Studies have shown that freshwater aquatic organisms are more sensitive to lead in soft than hard water.

## V. Controlling Lead Exposure

Over the last two decades EPA has taken a number of actions to control exposure to lead. Most notable of these actions has been the virtual removal of lead from gasoline. As a result of this action and the phase-out of lead solder in food cans by domestic manufacturers, it is estimated that the average PbB level in children has declined by 75 percent (from about 17 µg/dL to 4 µg/dL) over the past 15 years.

Despite this progress, several factors have prompted EPA to identify other sources of on-going lead exposure, especially exposure among children, and initiate additional actions. First, the level of concern at which lead may adversely affect human health continues to decrease. CDC revised its level of concern from 25 µg/dL to 10 µg/dL in 1990. Second, nearly nine percent of children continue to have PbB levels in excess of CDC's level of concern, with a higher incidence of elevated PbB reported for minorities living in urban areas (CDC, 1994). Third, other sources of lead (e.g., lead-based paint and drinking water) are the primary sources of exposure for segments of the population.

To coordinate EPA's lead activities, the Agency published the *Strategy for Reducing Lead Exposures* in February 1991, the goal of which is to reduce lead exposures to the fullest extent practicable. Two objectives have been used to set program priorities and gauge

program success: (1) Reduce significantly the incidence of PbB levels above 10 µg/dL in children while taking into account the associated costs and benefits; and (2) reduce significantly, through voluntary and mandatory actions, unacceptable lead exposures that are anticipated to pose risks to children, the general public, or the environment. EPA plans to achieve the strategy's goal and objectives through implementation of research, abatement, and regulatory and pollution prevention programs.

#### A. Research Program

The purposes of the research program are to: (1) Locate and assess, in terms of geography and media, the most serious lead risks; and (2) develop methods and tools to reduce these risks cost-effectively. Examples of accomplishments and on-going efforts include evaluation of low-cost lead-based paint (LBP) abatement techniques, development of LBP abatement sampling techniques and protocols, studies to analyze the effectiveness of corrosion control technologies in small public water supply systems to reduce lead levels, and continued development and review of the Integrated Environmental Uptake/Biokinetic (UBK) Model to assess the relationship between environmental lead exposure and PbB levels.

#### B. Abatement Program

1. *Lead-based paint.* EPA's abatement program for "in-place" lead focuses on two major sources of exposure: LBP and lead-contaminated soil. LBP is the most serious source of children's lead exposure. The Agency for Toxic Substances and Disease Registry (ATSDR) estimates that 12 million children are exposed to LBP at home and that nearly 6 million are exposed in homes with the highest concentrations of lead (houses built prior to 1940). Under a Memorandum of Understanding, EPA works closely with the U.S. Department of Housing and Urban Development (HUD) to address the LBP problem. EPA's efforts in this area have intensified with the enactment of Title X, "The Residential Lead-Based Paint Hazard Reduction Act of 1992" (the Act). Subtitle B of the Act, which amended TSCA by creating Title IV, provides for a comprehensive national approach to dealing with LBP in the nation's housing stock. One of the purposes of the Act is to reorient the Federal program from abatement of all residential LBP to abatement and in-place management of priority LBP hazards.

To date, EPA's LBP program has successfully implemented several initiatives. The Agency has established regional training and information centers and implemented a nationwide public outreach and education campaign. The outreach and education campaign consists of the National Lead Information Center, which operates the Lead Hotline and the Lead Clearinghouse. In addition, the National Lead Poisoning Prevention Education Campaign disseminates important information on residential LBP hazards through radio and television public service announcements.

The Act also directs EPA to develop several regulations designed to address residential LBP exposures. Under TSCA section 402(a)(1), EPA is developing training and certification requirements for individuals and contractors engaged in LBP activities (e.g., risk assessment, inspection, and abatement). These regulations will establish standards for performing LBP activities. This rulemaking also includes procedures for State and Indian Tribe program authorization under TSCA section 404(a) and a Model State Program under TSCA section 404(d). EPA issued proposed regulations under TSCA sections 402(a)(1), 404(a), and 404(d) in the *Federal Register* of September 2, 1994 (59 FR 45872).

Under TSCA section 403, EPA is developing health-based standards for identifying lead-based paint hazards, lead-contaminated dust, and lead-contaminated soil, and on July 14, 1994, issued guidance on this subject. EPA is developing regulations under TSCA section 406 and section 1018 of the Act requiring the disclosure of potential LBP hazards prior to renovation of target housing and the disclosure of known LBP and LBP hazards prior to the sale or lease of target housing.<sup>1</sup> The Notice of Proposed Rulemaking for TSCA section 406 was published on March 9, 1994 (59 FR 11108). In conjunction with this rulemaking, the Agency made a pamphlet on LBP hazards available to the public for review and comment (March 9, 1994; 59 FR 11119). EPA expects to issue a proposed rule under section 1018 of the Act later in 1994.

Under TSCA section 405(b), EPA has established the National Lead

Laboratory Accreditation Program (NLLAP) and developed protocols, criteria, and minimum performance standards for laboratories that analyze paint chip, dust, and soil samples for lead. The purpose of this program is to ensure that reliable laboratory services are available to support lead hazard detection and abatement activities. The Agency, in the first phase of the NLLAP program, is publishing proficiency test results for laboratories on a state-by-state basis. To implement the second phase of the program, EPA has executed Memoranda of Understanding with the American Industrial Hygiene Association (memorandum from Scott McMoran, USEPA to Gordon Banks, AIHA, December 10, 1993) and the American Association for Laboratory Accreditation (memorandum from Scott McMoran, USEPA to John Locke, AALA, December 1, 1993) establishing these institutions as laboratory accrediting organizations. The NLLAP program will recognize laboratories accredited by these organizations as capable of analyzing paint chip, dust, and soil samples for lead.

2. *Lead-contaminated soil.* The other major area of focus for EPA's abatement program for "in-place" lead is lead-contaminated soil. The Agency has completed a review draft of the Urban Soil Lead Abatement Demonstration Project (Three City Study) (USEPA, 1993). In addition, the Agency issued revised guidance on soil lead screening levels for Comprehensive Environmental Response, Compensation, and Liability Act and Resource Conservation and Recovery Act (RCRA) sites on July 14, 1994.

The Three City Study, authorized by section 111(a)(6) of the Superfund Amendments and Reauthorization Act (SARA), evaluated the effectiveness of soil lead abatement for reducing PbB levels in inner city children. The project, which analyzed data from Baltimore, Boston, and Cincinnati, demonstrated a clear relationship between environmental lead and FbB. Analysis of the data (peer review to be completed in 1994) indicates that lead in dust and paint were major contributors to elevated PbB levels in children and that PbB levels responded to remedial activity. Furthermore, analytical results from the three cities suggest that strategies to reduce overall lead exposure at a site and protect human health need to consider an array of sources including lead in soil, dust, and paint.

<sup>1</sup>Target housing is defined by section 1004 of Title X to be "any housing constructed prior to 1978, except housing for the elderly or persons with disabilities (unless any child who is less than 6 years of age resides or is expected to reside in such housing for the elderly or persons with disabilities) or any 0-bedroom dwelling. In the case of jurisdictions which banned the sale or use of lead-based paint prior to 1978, the Secretary [of Housing and Urban Development], at the Secretary's discretion, may designate an earlier date."

### C. Regulatory and Pollution Prevention Program

The third component of EPA's lead strategy is the regulatory and pollution prevention program. This program, which primarily focuses on existing and new uses and releases of lead, addresses lead exposures that are amenable to regulatory control or, in some cases, voluntary measures. These controls include waste management requirements, emissions restrictions, and limits on lead in products. Under its lead regulatory and pollution prevention program, EPA has completed a major rulemaking and initiated several other important actions.

The Agency published final regulations, promulgating maximum contaminant level goals and national primary drinking water regulations for controlling lead and copper in drinking water (40 CFR parts 141 and 142) on June 7, 1991 (56 FR 26460). These regulations established a maximum contaminant level goal at 0 µg/l for lead and an action level of 15 µg/l for lead. Public water supply systems failing to meet the action level based on sampling methods prescribed in the rule must initiate treatment actions that may include corrosion control, source water treatment, lead service line replacement, and public education. To date, EPA has received sampling data reports from three rounds of sampling. Round one covered large public water supply systems; round two covered large and medium-sized systems; and round three covered medium and small systems.

In an action to protect wildlife, EPA proposed regulations under section 6(a) of TSCA, limiting the manufacture, processing, and distribution in commerce in the United States, of certain size lead fishing sinkers on March 9, 1994 (59 FR 11122). Granting a section 21 petition by the Environmental Defense Fund, EPA proposed this regulatory action in response to information submitted in the petition which indicated that common loons, trumpeter swans, and birds from other avian species had died of lead poisoning after ingesting lead fishing sinkers. This proposed rulemaking also includes sinkers containing zinc because studies and other information obtained by EPA suggests that zinc adversely affects waterbirds and can cause mortality in avian species.

The Agency's regulatory efforts are complemented by initiatives to achieve voluntary compliance with lead exposure reduction goals. For example, EPA is currently participating in efforts by National Sanitation Foundation

International to develop a voluntary lead leaching standard for kitchen, bar, and lavatory faucets. The objective of this standard is to reduce the quantity of lead that leaches from brass faucets. Products that meet the standard based on test samples and analysis would be certified and appropriately labeled, indicating to consumers that the product contributes less lead to drinking and cooking water than faucets that fail to meet the certification requirements.

### VI. Review and Control of New Uses of Lead

#### A. Rationale

To date, EPA's programmatic efforts have focused on existing uses of lead, because there is substantial evidence that exposure to lead has adverse human health and environmental impacts. The Agency, however, is also concerned about new uses of lead, because they may result in new or increased exposures which may present an unreasonable risk of injury to human health and the environment. New or increased exposure to lead may arise from: (1) Increases in the volume of lead consumed; (2) increases in the concentration of lead in products; (3) new products containing lead; and (4) changes in product design that increase the amount of lead released from a product.

EPA believes that its concern about new uses is justified in light of lead's physical properties and low cost, attributes which make it an attractive raw material for a broad variety of commercial and consumer products. Consequently, the Agency believes that the regulation of existing uses alone may not be sufficient to reduce lead exposures to the greatest extent practicable. EPA should also evaluate and, if necessary, regulate new uses of lead before opportunities for exposure occur. The Agency further believes that addressing risks prior to commercial use is more effective than responding to exposures and risks after the use is introduced commercially. Because children are especially vulnerable to the impacts of lead, EPA is particularly concerned about new uses that could present risks to children. Consistent with the Agency's overall lead risk reduction program, EPA is also seeking to address risks to adults and the environment from new uses of lead. The Agency, therefore, is exploring the possibility of issuing significant new use rules for certain uses of elemental lead and lead compounds under section 5(a) of TSCA.

#### B. The SNUR Process

Section 5(a) of TSCA provides EPA with the authority to screen new uses of a chemical substance to determine whether these uses should be regulated. This screening function is accomplished through the SNUR process. EPA may issue a SNUR for a chemical substance after considering relevant factors, including: (1) The projected volume of manufacturing and processing of a chemical substance; (2) the extent to which a use changes the type or form of human or environmental exposure to a chemical substance; (3) the extent to which a use increases the magnitude and duration of human or environmental exposure to a chemical substance; and (4) the reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.

Having considered all the relevant factors, EPA can then issue a SNUR that identifies the chemical substance and specifies one or more uses as significant new uses. EPA also has the option to publish a SNUR that defines any use meeting specified criteria as a significant new use. Under a third option, EPA may list all past and existing uses of the substance and define any use not on that list as a significant new use.

After EPA promulgates a SNUR for a chemical substance, TSCA requires that a SNUN be submitted to the Administrator at least 90 days before the start of manufacturing or processing of the significant new use(s). Based on the information provided in the SNUN and other relevant data submitted, the Agency will evaluate the risk that the use presents to human health and the environment. EPA can, for good cause, extend the review period for a maximum of 90 days.

If, based on its review, the Agency determines that the significant new use may present an unreasonable risk of injury to human health or the environment but lacks the information necessary to make a definitive finding, it can issue an order to prohibit or limit the manufacturing, processing, or distribution in commerce of the use while it continues its risk evaluation. Once EPA has made its risk finding, it can either: (1) Take long-term action to prohibit or limit the manufacturing, processing, or distribution in commerce of the use if the use presents or will present unreasonable risk of injury to human health and the environment, or (2) take no action if it finds that there is no unreasonable risk. When making a determination of unreasonable risk, EPA

considers the risks of the use to human health and the environment, the benefits of the use, the availability of substitutes, and the economic consequences of any limits on the use.

In short, section 5 of TSCA gives EPA the authority to promulgate a SNUR based on factors related to exposure and volume. A SNUR requires notification of the significant new use(s). Following notification, the Agency evaluates the risk of the use(s) to determine whether it should limit or prohibit the use(s). EPA solicits comment on the effectiveness of using this approach for lead, as well as alternative approaches to protect human health and the environment from lead exposures.

### C. Formulating an Approach for Lead

To date, EPA has promulgated SNURs for substances where existing use is limited to a few applications and products. These SNURs typically identify all existing uses of the substance that is the subject of the SNUR. Lead, however, is used in hundreds of products and processes across many industries, due to its physical properties and low cost. The widespread use of lead makes the complete identification of all existing uses of lead extremely difficult. The traditional approach of first identifying all existing uses of a chemical substance, therefore, may not be appropriate for development of a lead SNUR.

To regulate new uses of lead in a sensible and protective manner, EPA intends to establish an alternative approach that can be used to identify significant new uses. This approach consists of two components: a targeting strategy and criteria for defining significant new uses.

1. *Targeting strategy.* The widespread use of lead in commerce has prompted EPA to develop a strategy that targets new lead uses where exposure to lead could reasonably be expected to occur as a result of the designed or anticipated use of the product. For example, the Agency would be concerned about a new use of lead in a product where lead could be inadvertently ingested by children (e.g., use of lead-based artists paints in home studios contributing lead to household dust). The strategy also targets new uses of lead that could result in adult and environmental exposure (e.g., heated lead solder for household electrical repairs that could produce inhalable vapors, spent lead shot that could contaminate habitat adjacent to shooting ranges). In contrast, EPA does not currently plan to focus on uses where human and/or environmental exposure would be less

likely to occur (e.g., new circuit boards used in computers and other electronics products, solder designed for industrial use in the electronics industry, batteries).

The Agency believes that using exposure to target new uses of lead is an appropriate tool and consistent with the SNUR authority under section 5 of TSCA. If, in response to a SNUR that EPA promulgates for specific lead uses, the Agency receives a SNUN, section 5 requires EPA to determine if further regulatory action is warranted by assessing whether the use presents or will present an unreasonable risk of injury to human health or the environment. By using exposure as the criterion for identifying new uses that would be subject to a SNUR, EPA intends to limit the SNUR and its notification requirements to those new uses where exposure is likely and thus have the potential to present unreasonable risk. Furthermore, this targeting strategy would eliminate from the requirements new uses where exposure is less likely and the potential for unreasonable risk may not exist.

Currently, EPA also does not plan to focus on classes of uses where other types of regulatory controls may be more appropriate than the SNUR approach or where existing controls are sufficient. In many industries, for example, lead compounds may be used during new or modified manufacturing processes (changes in manufacturing processes can be a factor in defining a significant new use), possibly resulting in occupational exposures. Similarly, improperly managed disposal of lead-containing products could result in exposure through releases to groundwater (landfilling) or the air (incineration). Although EPA is concerned about such exposures, the Agency believes that other regulatory mechanisms (e.g., Occupational Safety and Health Act, Clean Air Act, and RCRA authorities) are available, and in some cases in place, to address these problems.

Other uses of lead are exempt from regulation as "chemical substances" by EPA under section 3(2)(B) of TSCA. For example, exposure to lead through contamination of food and water from crystalware, ceramicware, and other housewares is regulated by the Food and Drug Administration (FDA) under authorities granted by the Federal Food, Drug, and Cosmetic Act and other statutes. The FDA, using its authorities, has established action levels for lead in ceramic foodware, including flatware, holloware, cups, mugs, and pitchers. The FDA has also issued a public advisory on the storage of alcoholic

beverages in crystalware, provided enforcement guidance for lead in wine, and has proposed a total ban on the use of tin-coated lead capsules on wine bottles.

EPA is currently examining five priority classes of use for identification of possible candidates for lead SNURs. Each class is defined in terms of a distinct exposure and/or environmental release scenario. These classes reflect the Agency's focus on health risks to children that may result from lead exposure.

The five use classes are:

1. Products used in water conveyance systems that come in contact with drinking water. The Agency has substantial evidence that lead leaches from components of water distribution systems and household plumbing (e.g., fixtures, fittings, solder, valves, pumps, meters, and tanks).

2. Products commonly used in and/or around the home where ordinary use (e.g., manipulation, grinding, sanding, heating) could result in release of lead to the residential environment. For example, the use of products such as home hobbyist supplies may contribute lead to household dust; lead vapors from products that are designed to be heated could be inhaled.

3. Products that could be mouthed by children where the lead-containing component in the product is reasonably accessible to children. Children could ingest lead by mouthing the lead-containing component (e.g., plastic toys where lead is used as a pigment or stabilizer and textiles with lead-based dyes).

4. Products that can release lead to the environment through exposure to weathering elements during use. Lead could be released through leaching or through deterioration of the product, contaminating dust and soil (e.g., sheet lead for roofing, lead caulk, traffic paint).

5. Products intended for non-residential (e.g. recreational, transportation, commercial, and industrial) use, where use necessarily results in uncontrolled release of lead to the environment. Examples include lead-containing products where use involves: (1) Combustion such as motor fuel additives, resulting in deposition of lead in the environment and (2) dispersal of the product in the environment such as fishing sinkers and ammunition containing lead shot.

For each of these five use classes, the following Table 1 provides examples of both the uses and the lead compounds or elemental forms of lead.



Table 1.—Illustrative Uses of Lead

Use Class	Uses	Lead Compounds/Forms of Lead
Products used in water conveyance systems that come in contact with drinking water	plumbing fixtures and fittings, joints, seals, solder, meters, pumps, valves, tanks	cast brass, wrought brass, lead solder
Products commonly used in and around the home where ordinary use could result in release of lead to the residential environment	stained glass, gold pencil, mosaic gold, photographic chemicals, water color pigments, lead solder for home repairs and home hobbyist use	lead came, lead iodide, lead oxides, lead bromide, lead fluoride, chromic acid, lead bis-carbinato, lead solder
Products that could be mouthed by children where the lead-containing component in the product is reasonably accessible to children	plastic toys, textile dyes, lead toy soldiers, toys painted with lead-based paint	lead oxides, lead nitrates, lead acetate, tribasic lead sulfate, dibasic lead stearate, lead dichloride
Products that can release lead to the environment through exposure to weathering elements during use	roofing, flashing, siding, gutters, eaves, seams, paint/varnish driers, industrial paint pigments, traffic paint	terne metal, lead sheet, caulking lead, lead solder, lead oxide, lead salts, lead arsenate, lead chromate
Products intended for nonresidential (e.g. recreational, transportation, commercial, industrial) use where use necessarily results in uncontrolled release to the environment	motor fuel (aviation gasoline, racing car fuel) additives, motor fuel odor modifier, fishing sinkers, lead shot for ammunition	tetra methyl, tetraethyl, triethylmethyl, diethyl, dimethyl, plumbate, disodium, lead weight, lead shot, lead styphnate

The purpose of Table 1 is to provide further clarification and understanding of these five use classes. Specific uses included in Table 1 are presented as illustrative examples and are not intended to represent an exhaustive list. Furthermore, these uses may be existing uses that would not be subject to the SNUR, depending on the final definition of "significant new uses."

Given the importance of this targeting scheme in regulating new uses of lead, the Agency is seeking comment on this approach. Specifically, EPA would like commenters to address the following issues: (1) The appropriateness of using the targeting approach described above to design lead SNURs, (2) whether the definition of any of the five use classes is particularly unclear with respect to the types of uses or products that might be covered, (3) whether any use classes listed in Table 1 should not be included in the targeting strategy and why, and (4) whether any use classes not listed in Table 1 should be included in the targeting strategy and why. EPA is particularly interested in relevant data that commenters may possess which suggest that SNURs are or are not appropriate for specific use classes.

**2. Criteria for identifying significant new uses.** The second element of EPA's approach for regulating new uses of lead is criteria for defining significant new

uses of lead. These criteria may include the development of a new product/use (i.e., product model or line), change in concentration of lead in a product/use, change in surface area and other factors that affect the amount of lead released from a product, and/or change in total volume of lead for a product/use. Because lead is used in a broad range of products involving numerous industries, it is likely that the Agency will develop criteria that are specific to particular products/uses rather than one set of criteria that would be applied uniformly.

When selecting criteria, EPA will endeavor not to define, as significant new uses, products or processes that have been developed specifically to reduce lead exposures. EPA does not wish and does not intend that any SNUR for lead impede innovations that would reduce risks to human health and the environment.

To aid in developing these criteria, EPA plans to establish a baseline inventory of existing uses in the five use classes identified in Table 1. The baseline inventory will include at least the following data elements for each identified product/use: Product/use identification, product/use description; lead compound (and CAS number) or form of elemental lead; median lead concentration; range of lead

concentration; other design factors associated with the level of lead released from the product; the frequency with which the design of the use/product changes; and total volume of lead consumed annually for the product/use. These data will serve several purposes. First, they will enable EPA to identify existing uses of lead. Only significant new uses will be subject to regulation under section 5 of TSCA. Second, these data will improve the Agency's understanding of existing uses and help EPA select appropriate criteria for effectively identifying and controlling significant new uses of lead.

The Agency invites commenters to submit information of the type described in the preceding paragraph for any lead-containing product/use belonging to one of the five priority use classes identified in Table 1. For purposes of this Notice, EPA defines a lead-containing use/product as a use/product where lead is intentionally introduced at any stage of manufacturing or processing. EPA is not currently examining uses/products that contain lead merely as an inadvertent contaminant. EPA is also interested in data that commenters may possess on human and environmental exposure, bioavailability, and risks associated with any such products or uses. Although the Agency does not normally

consider the costs and/or availability of substitutes when defining new uses for a SNUR, commenters with this kind of information are welcome to submit the information if they feel that this information might be useful to the Agency. Data provided by commenters will help the Agency to compile a baseline inventory of existing lead-containing products and uses and will help in the selection of criteria for defining significant new uses of lead.

Currently, EPA is not interested in receiving information for uses/products that are not described by any of the five priority class definitions unless the use/product relates to an additional use class that the commenter believes EPA should consider when developing a SNUR. Commenters who are uncertain (1) if a specific use/product fits into any of the five classes and/or (2) about the type of use/product data that EPA would like commenters to submit should address their questions to the technical contact listed under "FOR FURTHER INFORMATION CONTACT" in this document.

#### VII. Rulemaking Record and Electronic Filing of Comments

A record has been established for this ANPR under docket number "OPPTS-50618" (including comments and data submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI (see Unit VIII. of this document), is available for inspection from noon to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in the TSCA Nonconfidential Information Center (NCIC) (also known as the TSCA Public Docket Office), Rm. NE-B607, 401 M St., SW., Washington, DC 20460.

As part of an interagency "streamlining" initiative, EPA is experimenting with submission of public comments on selected rulemaking actions electronically through the Internet in addition to accepting comments in traditional written form. This ANPR is one of the first rulemaking actions selected by EPA for this experiment. From the experiment, EPA will learn how electronic commenting works, and any problems that arise can be addressed before EPA adopts electronic commenting more broadly in its rulemaking activities. Electronic commenting through posting to the EPA Bulletin Board or through the Internet using the ListServe function raise some novel issues that are discussed below in this Unit.

To submit electronic comments, persons can either "subscribe" to the Internet ListServe application or "post" comments to the EPA Bulletin Board. To "Subscribe" to the Internet ListServe application for this ANPR, send an e-mail message to:

listserver@unixmail.rtpnc.epa.gov that says "Subscribe RIN-2070-AC37 <first name> <last name>." Once you are subscribed to the ListServe, comments should be sent to:

RIN-2070-AC37@unixmail.rtpnc.epa.gov.

For online viewing of submissions and posting of comments, the public access EPA Bulletin Board is also available by dialing 202-488-3671, enter selection "DMAIL," user name "BB—USER" or 919-541-4642, enter selection "MAIL," user name "BB—USER." When dialing the EPA Bulletin Board type <Return> at the opening message. When the "Notes" prompt appears, type "open RIN-2070-AC37" to access the posted messages for this document. To get a listing of all files, type "dir/all" at the prompt line.

Electronic comments can also be sent directly to EPA at:

Docket-OPPTS@epamail.epa.gov.

To obtain further information on the electronic comment process, or on submitting comments on this ANPR electronically through the EPA Bulletin Board or the Internet ListServe, please contact John A. Richards (Telephone: 202-260-2253; FAX: 202-260-3884; Internet: richards.john@epamail.epa.gov).

Persons who comment on this ANPR, and those who view comments electronically, should be aware that this experimental electronic commenting is administered on a completely public system. Therefore, any personal information included in comments and the electronic mail addresses of those who make comments electronically are automatically available to anyone else who views the comments. Similarly, since all electronic comments are available to all users, commenters should not submit electronically any information which they believe to be CBI. Such information should be submitted only directly to EPA in writing as described in Unit VIII. of this document.

Commenters and others outside EPA may choose to comment on the comments submitted by others using the RIN-2070-AC37 ListServe or the EPA Bulletin Board. If they do so, those comments as well will become part of EPA's record for this rulemaking. Persons outside EPA wishing to discuss comments with commenters or otherwise communicate with

commenters but not have those discussions or communications sent to EPA and included in the EPA rulemaking record should conduct those discussions and communications outside the RIN-2070-AC37 ListServe or the EPA Bulletin Board.

The official record for this rulemaking, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer all comments received electronically in the RIN-2070-AC37 ListServe or the EPA Bulletin Board, in accordance with the instructions for electronic submission, into printed, paper form as they are received and will place the paper copies in the official rulemaking record which will also include all comments submitted directly in writing. All the electronic comments will be available to everyone who obtains access to the RIN-2070-AC37 ListServe or the EPA Bulletin Board; however, the official rulemaking record is the paper record maintained at the address in "ADDRESSES" at the beginning of this document. (Comments submitted only in written form will not be transferred into electronic form and thus may be accessed only by reviewing them in the TSCA Nonconfidential Information Center as described above.)

Because the electronic comment process is still experimental, EPA cannot guarantee that all electronic comments will be accurately converted to printed, paper form. If EPA becomes aware, in transferring an electronic comment to printed, paper form, of a problem or error that results in an obviously garbled comment, EPA will attempt to contact the comment submitter and advise the submitter to resubmit the comment either in electronic or written form. Some commenters may choose to submit identical comments in both electronic and written form to ensure accuracy. In that case, EPA requests that commenters clearly note in both the electronic and written submissions that the comments are duplicated in the other medium. This will assist EPA in processing and filing the comments in the rulemaking record.

As with ordinary written comments, EPA will not attempt to verify the identities of electronic commenters nor to review the accuracy of electronic comments. EPA will take such commenters and comments at face value. Electronic and written comments will be placed in the rulemaking record without any editing or change by EPA except to the extent changes occur in the process of converting electronic comments to printed, paper form.

If it chooses to respond officially to electronic comments on this ANPR, EPA will do so either in a notice in the *Federal Register* or in a response to comments document placed in the rulemaking record for this ANPR. EPA will *not* respond to commenters electronically other than to seek clarification of electronic comments that may be garbled in transmission or conversion to printed, paper form as discussed above. Any communications from EPA employees to electronic commenters, other than those described in this paragraph, either through Internet or otherwise are not official responses from EPA.

#### VIII. Confidential Business Information

A person may assert a claim of confidentiality for any information, including all or portions of written comments or data, submitted to EPA in connection with this advanced notice of proposed rulemaking. Information claimed as confidential should not be submitted electronically as described in Unit VII. of this document. Any person who submits a comment or data subject to a claim of confidentiality must also submit a nonconfidential version. Any claim of confidentiality must accompany the information when it is submitted to EPA. Persons must mark information claimed as confidential by circling, bracketing, or underlining it,

and marking it with "CONFIDENTIAL" or some other appropriate designation. EPA will disclose information subject to a claim of confidentiality only to the extent permitted by section 14 of TSCA and 40 CFR part 2, subpart B. If a person does not assert a claim of confidentiality for information at the time it is submitted to EPA, EPA may make the information public without further notice to that person. Any information submitted electronically as described in Unit VII. will be available to the public immediately without restriction.

#### IX. Executive Order 12866

Under Executive Order 12866 (58 FR 51735, October 4, 1993), the Agency must determine whether the regulatory action is "significant" and therefore subject to review by the Office of Management and Budget (OMB) and the requirements of the Executive Order. Under section 3(f), the order defines a "significant regulatory action" as an action that is likely to result in a rule: (1) Having an annual effect on the economy of \$100 million or more, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities (also referred to as "economically significant"); (2) creating serious

inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order.

Pursuant to the terms of this Executive Order, OMB has determined that this ANPR is a "significant regulatory action" because a lead SNUR may raise novel legal or policy issues. As such, this action was submitted to OMB for a 10-day review, and any comments or changes made in response to OMB suggestions or recommendations have been documented in the public record.

#### List of Subjects in 40 CFR Part 721

Environmental protection, Chemicals, Hazardous materials, Recordkeeping and reporting requirements, Significant new uses.

Dated: September 20, 1994.

Lynn R. Goldman,

*Assistant Administrator for Prevention, Pesticides and Toxic Substances.*

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